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7590

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SALIWANCHIK LLOYD & SALIWANCHIK
2421 N W 41ST STREET
SUITE A 1
GAINESVILLE, FL 32606-6669

EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

17

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,676

Applicant(s)

CRISANTI, ANDREA

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-35 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) 38,39 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-35,37,40,41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 25-35, 37-45 are pending in the application. Claims 38, 39 and 42 are withdrawn from consideration for being directed to non-elected subject matter. Claims 25-35, 37, 40, 41, 43-45 are currently under examination.

This Office Action is in response to the Amendment filed on 7/15/03.

Response to Amendment

Claims 25-35, 37, 40, 41 and newly added claims 43-45 stand rejected under 35 U.S.C. 112 1st paragraph (written description) for reasons set forth of the record mailed on 4/9/03 and further discussed below.

Claims 25-35, 37, 40, 41 and newly added claims 43 and 45 stand rejected under 35 U.S.C. 112 1st paragraph (scope of enablement) for reasons set forth of the record mailed on 4/9/03 and further discussed below.

Response to Arguments

Election/Restrictions

Applicants request that claims 38, 39 and 42 be rejoined for examination upon the allowance of the elected invention. Such request is not considered at present because the elected invention is not allowed.

Claim Rejections - 35 USC § 112

Claims 25-35, 37, 40, 41 and newly added claims 43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the written description requirement is met because the claimed functional variants retain the functional ability of the antennapedia to permit translocation. Applicants further argue that the specification refers to several publications which disclose additional variants of the antennapedia homeodomain. Applicants also assert that the specification teaches methods that can identify functional activity of such variants.

Applicants thus conclude that the specification provides a sufficient written description that conveys the skilled artisan that the Applicants was in possession of the claimed invention at the time the application was filed.

The above arguments have been fully considered but deemed unpersuasive. As discussed in the previous office action, when the claimed invention encompasses a large genus, the specification needs to describe a representative number of species by their complete structure or other identifying characteristics to satisfy the written description requirement. Although the specification discloses a antennapedia homeodomain and refers to several publications which disclose additional variants of the antennapedia homeodomain, the specification fails to teach which part or what kind of mutations that are responsible for the function of ant homeodomain which include translocation, nuerotropic activity and DNA binding. As such, even for the claims that recite "functional variants," the structural functional relationship is missing. The specification teaches methods for testing the activity of those variants, however, such methods do not demonstrate possession of the invention because those variants are unknown. Applicants are reminded that although the specification does not have to teach each and every variant of the

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invention, it must describe a core structure shared by these variants to meet the written description requirement. In the instant case, the specification fails to disclose such core structure. Therefore, this rejection is maintained.

Claims 25-35, 37, 40, 41 and newly added claims 43, 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a conjugate consisting the fusion protein of homeodomain of the ant and a second protein of interest that is at least 100 amino acid in length, and optionally an amino acid tail that binds to an immobilized substrate, wherein the conjugate is not denatured, does not reasonably provide enablement for any conjugate comprising ant homeodomain, a second protein that is at least 100 amino acid in length, and other molecules such as nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

In response to this rejection, Applicants argue that the specification teach a conjugate of the invention comprise a GAL4 protein or histone which can bind nucleic acids for delivery into a cell. Applicants further indicate that the specification teaches the preparation of a conjugate comprising OCT-2.4, which is a DNA binding protein. Applicants thus conclude that claims are enabled for a conjugate comprising ant homeodomain and a second protein that is at least 100 amino acid in length and further comprises a nucleic acid bound to said second protein. Further, Applicants argue that such claimed conjugate can deliver DNA for gene therapy application or delivering reporter gene, therefore has a utility. Lastly, Applicants argue that the enablement of

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the invention depends on the first region being non-denatured regardless whether second region is denatured or not.

The above arguments have been fully considered but deemed non-persuasive. The invention is not enabled for its full scope for reasons set forth of the record mailed on 4/9/03. Although the specification discloses that a conjugate comprising ant domain and GAL4, histone or OCT-2.4 can be made in form of fusion protein, the specification fails to disclose whether such conjugate may bind a gene of interest and deliver to it to a cell. The art teaches that protein such as transcription factors or histone can bind nucleic acid in its natural form but not when it is denatured. In addition, the state of art at the time of filing considers gene therapy as a highly unpredictable field. The technical difficulties in efficient delivery, sustained level of expression and safety concerns are factors that determine the successful outcome of the therapy. The specification fails to teach a method that would overcome such unpredictability by using the conjugate system. For example, the conjugate would be degraded in a cell, is the nucleic acid going to express the therapeutic gene at a high enough level to cause a therapeutic effect? The specification not only has to teach a specific utility of the invention, it also has to teach how to use the invention for its disclosed utility. In the instant case, the specification fails to teach how to make a conjugate that delivers a nucleic acid, nor does it teach how to use claimed conjugate according to its disclosed utility. Therefore, the invention is not enabled to its full scope and the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 38, 39 and 42 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
RESEARCHER